

REMARKS

Claims 17, 24, 30, and 44 are currently amended and claims 20 and 21 are canceled herein. Accordingly, claims 17-19 and 22-44 remain pending.

Rejection under 35 USC 112

The office action rejects claims 17-44 as indefinite.

With reference to claim 17, the examiner argues that the terms “ultrafiltrate” and “stream of filtered blood” are “both conventionally understood to refer to blood fluid which has permeated through a blood filter or membrane filter pores.” To applicant’s knowledge, no such convention exists with respect to the term “stream of filtered blood” in connection with hemofiltration. A person of ordinary skill in the art would certainly understand that a hemofilter, which creates an ultrafiltrate (widely understood to refer to the permeate – a fluid that contains molecules that have passed through pores of the hemofilter), also creates a second stream of retentate, which contains molecules that have not passed through the pores. The retentate might be said to have been “filtered” because it is also widely understood that hemofilters can purify a stream containing molecules by, for example, allowing certain molecules, including water, to permeate through pores in hollow fibers and to exit an ultrafiltrate port.

Even if the foregoing is not the ordinary meaning, the applicants are allowed to be their own lexicographer. See, e.g., MPEP 2111.01(IV). The application makes a clear distinction between “ultrafiltrate” and “filtered blood”. For example, page 14, line 22-26 of the application state: “Very large pore hemofilter 102 receives a stream of blood from patient or mammal 100 and removes ultrafiltrate from the stream of blood and thereby creates a stream of filtered blood and a stream of ultrafiltrate flowing through tubing 112.” See also Fig. 2 and the discussion accompanying Fig. 1. For at least these reasons, applicant respectfully submits that claim 17 is not indefinite.

The examiner also rejected claim 24 on similar grounds. Claim 24 is amended herein to clarify the relationship between the hemofilter, pores, blood, ultrafiltrate and return stream,

and for at least the reasons stated above with regard to claim 17, applicant respectfully submits that claim 24 is not indefinite.

The examiner also rejected claim 20 as being in conflict with previously amended claim 17 and rejected claim 21 as being redundant with previously amended claim 17. Applicant has canceled claims 20 and 21 without prejudice in order to comport with previously amended claim 17.

The Nose reference

The pending claims have been rejected as anticipated by Nose (US 4,492,940), or as obvious over Nose in combination with other references. However, because it fails to teach or suggest the invention, Nose cannot be used to maintain a rejection of the presently amended claims under either 35 USC §102 or under 35 USC §103.

Nose teaches the use of a hemofilter with pores sized to allow passage of IgG (an immunoglobulin having a molecular weight of about 160 kDa) together with albumin (MW of roughly 70 kDa) from the blood of a patient, while retaining IgM (an immunoglobulin having a molecular weight of about 950 kDa), and comparably large molecules including rheumatoid factor. For example, Nose teaches that “the membrane **permits permeation of albumin and IgG** in the blood plasma and inhibits penetration of cholesterol and IgM as mentioned above.” Nose at col. 3, ll. 50-53. Thus, Nose teaches selecting a molecular weight cutoff that divides the blood components into two streams (i) a permeate containing IgG, albumin and smaller molecules, all of which pass through the filter’s pores, and (ii) a retentate containing IgM and other large molecules or complexes that do not pass through the pores. See also Nose col. 9, ll. 35-52 and Fig. 4 (showing separation of the albumin/IgG fraction from the IgM/rheumatoid factor fraction). However, the Nose filter is said to give “a bare decrease in levels of albumin.” Nose, at col. 9, ll. 25-26, emphasis added. In order for this to be true, the ultrafiltrate must be returned to the patient. Because Nose seeks to remove IgM and rheumatoid factor, at least a portion of the retentate must be discarded.

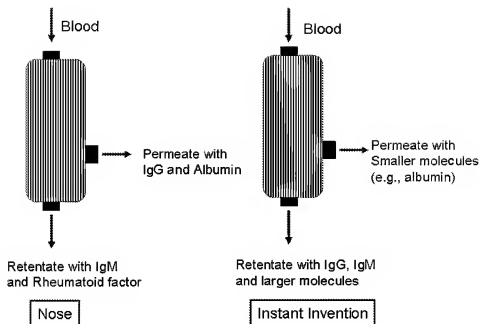
It is readily apparent from the citation of particular teachings purported to be found in Nose that the office action misinterprets that reference. For example, the office action contends that col. 2, ll. 30-36 of Nose teaches a filter that “sieves toxic and toxic molecules while avoiding significant amounts of immunoglobulins from the blood (IgG).” Office action

at p. 3, ll. 21-22, and p. 5, emphasis added. That passage of Nose discloses (emphasis added): "...possible to **inhibit permeation of noxious components such as IgM** (molecular weight: 950,000), cholesterol, immune complexes or rheumatoid factors **without loss of albumin and IgG** (molecular weight about 160,000)..." Taken in the context of the immediately preceding sentence (Nose, col. 2, ll. 16-26) and the rest of the disclosure, Nose separates albumin and IgG from IgM.

Perhaps the particular confusion is that the office action ignores the fact the IgM is an immunoglobulin, as is apparent from the office action's use of parenthetical "igG" (sic). This is a clear misstatement of the meaning of the term "immunoglobulin." As is well known in the art, the letters "Ig" in both of the terms "IgM" and "IgG" represent "Immunoglobulin". When understood in this light, it becomes apparent that the Nose filter, which allows teasing apart of IgG from IgM immunoglobulin fractions, sieves immunoglobulins, since such a filter will, by design, remove a significant amount of one or the other type of immunoglobulin.

Additionally, the office action is incorrect to more specifically assert that Nose avoids sieving significant amounts of IgG. Any filter that uses pores to separate molecules of widely different sizes will surely allow passage of the smaller molecules through the pores and retention of the larger molecules in the stream. This relation is explicitly disclosed in Nose. See. e.g., Nose at col 2, ll. 21-38. Because, as is disclosed by Nose, IgG molecules are about 6-fold smaller than IgM molecules, the IgG molecules will pass through the pores and into the ultrafiltrate and the IgM molecules will be retained in the stream of filtered blood. Thus, Nose clearly teaches a filter that sieves significant amounts of IgG.

In contrast, the instant invention as circumscribed by the pending claims teaches a **hemofilter that is adapted to exclude immunoglobulins, of which IgG is one**, in order to remove toxins while maintaining the immunity of the patient. For example, independent claim 17 recites a blood filter operable to "avoid removal of significant amounts of immunoglobulins," Nose does not teach or suggest such a hemofilter. The following figure schematically highlights this key difference between Nose and the instant invention.



Additionally, the office action is mistaken in finding similarity between Nose and the instant application by purporting that the Nose filter creates an “ultrafiltration” stream that is removed and a filtered stream that is returned to the patient. Office action at page 3, ll. 23-24 and page 5, ll. 16-18. This characterization is unfair because these claims use the term “ultrafiltrate,” not “ultrafiltration.” By conflating these terms, the office action implies that the two output streams of an ultrafiltrate are equivalent. This is clearly not the case, because if it were so, an ultrafilter would have no effect beyond that of a T-junction (dividing one stream into two equivalent streams). Nose fails to disclose such circuit. In fact, if the ultrafiltrate from the Nose filter were to be removed and the retentate returned to the patient, the effect on the patient would be exactly opposite to that sought by Nose – the IgM’s would be returned to the patient and the albumin and IgG removed. The present application seeks to remove smaller molecules from the blood while retaining larger molecules, while Nose

seeks to remove larger molecules while retaining smaller molecules. Because it seeks a different result, the present application describes returning the retentate (i.e., the filtered stream) and disposing of at least part of the ultrafiltrate, while Nose implies the opposite.

For at least the foregoing reasons, Nose fails to teach every element of the invention as claimed in the independent claims. Accordingly, Nose cannot be used to reject the invention under 35 U.S.C. §102. Moreover, a rejection under 25 U.S.C. §103 is not proper because Nose does not teach all of the limitations of the claims none of the secondary references cited in the office action provide or suggest the missing limitations. In general, the rejection for obviousness set forth in the office action is predicated on a misinterpretation of Nose, as explained above in connection with the rejection for anticipation. The dependent claims are patentable for at least the same reasons.

Applicants also note that the office action confuses the word "clean" in conjunction with the target receptor molecules with the concept of sterilization. See, e.g., office action at page 6, ll. 1-15. As defined in the application, the term "clean target receptor molecule" refers to a receptor molecule or a carrier molecule which is not contaminated with or bound with a target molecule."

Claims 17 and 30 are amended herein to correct obvious typographical errors and extraneous markings, and not for any reason related to patentability. Claim 44 is amended herein to correct the claim's dependency.

Applicants submit that, for at least the foregoing reasons, all claims pending in the application are allowable over the art of record. Early notice to that effect is respectfully solicited. Reconsideration of the application and issuance of a notice of allowance are respectfully requested. Applicants hereby petitions for a three month extension of time and requests that this and any other fee required for timely consideration of this application be applied and charged to Deposit Account No. 19-4972. The Examiner is requested to telephone the undersigned if any matters remain outstanding so that they may be resolved expeditiously.

Respectfully submitted,

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